

IMPROVING REGULATORY TRANSPARENCY FOR NEW MEDICAL THERAPIES ACT

SEPTEMBER 19, 2014.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. GOODLATTE, from the Committee on the Judiciary,
submitted the following

R E P O R T

[To accompany H.R. 4299]

[Including cost estimate of the Congressional Budget Office]

The Committee on the Judiciary, to whom was referred the bill (H.R. 4299) to amend the Controlled Substances Act with respect to drug scheduling recommendations by the Secretary of Health and Human Services, and with respect to registration of manufacturers and distributors seeking to conduct clinical testing, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The Amendment

The amendment is as follows:

Strike all that follows after the enacting clause, and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Improving Regulatory Transparency for New Medical Therapies Act”.

SEC. 2. SCHEDULING OF SUBSTANCES INCLUDED IN NEW FDA-APPROVED DRUGS.

Section 201(a) of the Controlled Substances Act (21 U.S.C. 811(a)) is amended by adding at the end the following: “Any such proceedings initiated at the request of the Secretary under this subsection to control a drug or other substance not previously scheduled, where the Secretary has recommended the drug or other substance be placed in schedule II, III, IV, or V, shall be commenced not later than 120 days after receipt of written recommendations from the Secretary. The final rule shall be issued not later than 60 days after the date on which both the public comment period has closed and the drug or other substance is the subject of an approved new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act, unless a hearing on the proposed rule is granted by the Attorney General.”.

SEC. 3. ENHANCING NEW DRUG DEVELOPMENT.

Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

“(i)(1) For the purposes of registration to manufacture a controlled substance under subsection (d) of this section for use only in a clinical trial, the Attorney General shall register an applicant or serve an order to show cause upon an applicant pursuant to section 304(c) of this Act not later than 180 days after receipt of an application and all information the Attorney General deems necessary to make a determination under subsection (d).

“(2) For the purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with regulations issued by the Attorney General, issue a notice of application not later than 90 days after receipt of an application and all information the Attorney General deems necessary to issue a notice of application. Following the close of the comment period and receipt of all information the Attorney General deems necessary to make a determination under subsection (a), the Attorney General shall register an applicant or serve an order to show cause upon an applicant pursuant to section 304(c) of this Act within 180 days, unless a hearing on the application has been granted by the Attorney General pursuant to section 1008(i) of the Controlled Substances Import and Export Act.”.

Purpose and Summary

H.R. 4299 improves patient access to new and innovative medications by streamlining the process for scheduling new drugs under the Controlled Substances Act (CSA). H.R. 4299 also amends the Drug Enforcement Administration’s (DEA) approval process for drugs to be used in clinical trials by requiring that, for the purposes of a DEA registration to manufacture or distribute a controlled substance for use only in connection with clinical trials, the DEA must either register the manufacturer for the purposes of a clinical trial or serve an order to show cause on the applicant within 180 days.

Background and Need for the Legislation

Under current law, drugs and substances that have not been marketed previously in the United States and that have the potential for abuse and/or dependency must be approved by the Food and Drug Administration (FDA), and also must be scheduled under the CSA by the DEA before a company can begin marketing its product.

During FDA's approval process, the agency examines the abuse and dependency potential of the new drug and makes a scheduling recommendation through the Secretary of HHS to the DEA (through the Attorney General). In formulating its recommendations, FDA conducts an eight-part test outlined in Section 201(c) of the CSA.¹ There is no time limit on the FDA approval process. Once it receives the FDA's report and recommendations, the DEA also utilizes the eight-part test in Section 201(c) to conduct its review. FDA's decisions related to scientific and medical matters² are binding on the DEA, but FDA's scheduling recommendation is only a recommendation, which DEA must consider in its independent determination. In recent years, some companies have complained that the length of time DEA has taken in its scheduling decisions has delayed their product launches, which has denied patients access to the new therapies. As amended, H.R. 4299 requires that, for drugs that FDA has recommended be placed in Schedules II, III, IV, and V, DEA must initiate the scheduling process not later than 120 days after it receives the FDA's analysis and recommendations. It also requires that the DEA issue a final rule not later than 60 days after the date on which both the public comment period has closed and the FDA has approved the drug.

H.R. 4299 also amends the DEA approval process for drugs to be used in clinical trials, because there have been complaints from the pharmaceutical industry that DEA has taken too much time to make scheduling decisions for drugs to be used only in clinical trials. It would do this by requiring that, for the purposes of a DEA registration to manufacture or distribute a controlled substance for use only in connection with clinical trials, the DEA must either register the manufacturer for the purposes of a clinical trial or serve an order to show cause on the applicant within 180 days. H.R. 4299 also provides that this time period does not begin until the application and all necessary information is submitted to DEA, which includes the notice and comment period required under the regulations for applications to manufacture Schedule I or II drugs.

Hearings

The Committee on the Judiciary held no hearings on H.R. 4299.

Committee Consideration

On September 10, 2014, the Committee met in open session and ordered the bill H.R. 4299 favorably reported with an amendment, by voice vote, a quorum being present.

Committee Votes

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the Committee advises that there were no recorded votes during the Committee's consideration of H.R. 4299.

¹21 U.S.C. §811(c).

²See 21 U.S.C. §811(c)(2) and (3).

Committee Oversight Findings

In compliance with clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee advises that the findings and recommendations of the Committee, based on oversight activities under clause 2(b)(1) of rule X of the Rules of the House of Representatives, are incorporated in the descriptive portions of this report.

New Budget Authority and Tax Expenditures

Clause 3(c)(2) of rule XIII of the Rules of the House of Representatives is inapplicable because this legislation does not provide new budgetary authority or increased tax expenditures.

Congressional Budget Office Cost Estimate

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the Committee sets forth, with respect to the bill, H.R. 4299, the following estimate and comparison prepared by the Director of the Congressional Budget Office under section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 17, 2014.

Hon. BOB GOODLATTE, CHAIRMAN,
Committee on the Judiciary,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 4299, the “Improving Regulatory Transparency for New Medical Therapies Act.”

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Mark Grabowicz, who can be reached at 226–2860.

Sincerely,

DOUGLAS W. ELMENDORF,
DIRECTOR.

Enclosure

cc: Honorable John Conyers, Jr.
Ranking Member

H.R. 4299—Improving Regulatory Transparency for New Medical Therapies Act.

As ordered reported by the House Committee on the Judiciary
on September 10, 2014.

H.R. 4299 would modify the administrative procedures followed by the Department of Justice in regulating new drugs that are already approved by the Food and Drug Administration and in authorizing drugs to be used in clinical trials. The legislation would aim to streamline the current review and approval process. CBO estimates that implementing the bill would have no significant costs to the Federal Government. Enacting the legislation would

not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 4299 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

On June 26, 2014, CBO transmitted a cost estimate for H.R. 4299 as ordered reported by the House Committee on Energy and Commerce on June 10, 2014. The cost estimates are the same.

The CBO staff contact for this estimate is Mark Grabowicz. The estimate was approved by Theresa Gullo, Deputy Assistant Director for Budget Analysis.

Duplication of Federal Programs

No provision of H.R. 4299 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

Disclosure of Directed Rule Makings

The Committee estimates that H.R. 4299 specifically directs to be completed no specific rule makings within the meaning of 5 U.S.C. 551.

Performance Goals and Objectives

The Committee states that pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, H.R. 4299 streamlines the process for scheduling new drugs under the Controlled Substances Act.

Advisory on Earmarks

In accordance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 4299 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(e), 9(f), or 9(g) of Rule XXI.

Section-by-Section Analysis

The following discussion describes the bill as reported by the Committee.

Sec. 1. Short title. Section 1 sets forth the short title of the bill as the Improving Regulatory Transparency for New Medical Therapies Act.

Sec. 2. Scheduling of Substances Included in New FDA-Approved Drugs. Section 2 imposes a statutory timeline on DEA for scheduling new drugs. Specifically, it requires that for drugs that FDA has recommended be placed in Schedules II, III, IV, and V, DEA initiate the scheduling process not later than 120 days after it receives the FDA's analysis and recommendations. It also requires that the DEA issue a final rule not later than 60 days after the date on which both the public comment period has closed and the FDA has approved the drug. Though it imposes new statutory timelines on DEA, H.R. 4299 as reported maintains DEA's existing

statutory authority to conduct its own analysis of drugs for scheduling purposes, as required under 21 U.S.C. 811(c), and preserves the authority of the Attorney General to schedule a drug in his discretion, as required in 21 U.S.C. 811(a).

Sec. 3. Enhancing New Drug Development. Section 3 requires DEA to either register a manufacturer for the purposes of a clinical trial or serve an order to show cause on the applicant within 180 days. Section 3 also provides that this time period does not begin until the application and all necessary information is submitted to DEA, which includes the notice and comment period required under the regulations for applications to manufacture Schedule I or II drugs.

Changes in Existing Law Made by the Bill, as Reported

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italics and existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

TITLE II—CONTROL AND ENFORCEMENT

SHORT TITLE

SEC. 100. This title may be cited as the “Controlled Substances Act”.

* * * * *

PART B—AUTHORITY TO CONTROL; STANDARDS AND SCHEDULES

AUTHORITY AND CRITERIA FOR CLASSIFICATION OF SUBSTANCES

SEC. 201. (a) The Attorney General shall apply the provisions of this title to the controlled substances listed in the schedules established by section 202 of this title and to any other drug or other substance added to such schedules under this title. Except as provided in subsections (d) and (e), the Attorney General may by rule—

(1) * * *

* * * * *

Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rule-making procedures prescribed by subchapter II of chapter 5 of title 5 of the United States Code. Proceedings for the issuance, amendment, or repeal of such rules may be initiated by the Attorney General (1) on his own motion, (2) at the request of the Secretary, or (3) on the petition of any interested party. *Any such proceedings initiated at the request of the Secretary under this subsection to control a drug or other substance not previously scheduled, where the Secretary has recommended the drug or other substance be placed in schedule II, III, IV, or V, shall be commenced not later than 120*

days after receipt of written recommendations from the Secretary. The final rule shall be issued not later than 60 days after the date on which both the public comment period has closed and the drug or other substance is the subject of an approved new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act, unless a hearing on the proposed rule is granted by the Attorney General.

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PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

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REGISTRATION REQUIREMENTS

SEC. 303. (a) * * *

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(i)(1) For the purposes of registration to manufacture a controlled substance under subsection (d) of this section for use only in a clinical trial, the Attorney General shall register an applicant or serve an order to show cause upon an applicant pursuant to section 304(c) of this Act not later than 180 days after receipt of an application and all information the Attorney General deems necessary to make a determination under subsection (d).

(2) For the purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with regulations issued by the Attorney General, issue a notice of application not later than 90 days after receipt of an application and all information the Attorney General deems necessary to issue a notice of application. Following the close of the comment period and receipt of all information the Attorney General deems necessary to make a determination under subsection (a), the Attorney General shall register an applicant or serve an order to show cause upon an applicant pursuant to section 304(c) of this Act within 180 days, unless a hearing on the application has been granted by the Attorney General pursuant to section 1008(i) of the Controlled Substances Import and Export Act.

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